

REMARKS/ARGUMENTS

The rejections presented in the Office Action dated May 25, 2007 (hereinafter Office Action) have been considered. Claims 1-62 remain pending in the application.

Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

Claims 1-3, 10-19, 20, 24-27, 36-39, 44-55, and 59-62 are rejected based on 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 7,031,773 to *Levine et al.* (hereinafter "*Levine*").

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102. The Applicant respectfully submits that *Levine* does not teach each and every element of independent claims 1, 20, 36, 61, and 62, and therefore fails to anticipate these claims.

The Applicant's independent claims 1, 20, 36, 61, and 62 each recite, among other features, some variation of disabling atrial antitachycardia pacing (ATP) therapy in response to a measured impedance deviating from a threshold.

Levine discloses an auto-capture technique where, if an impedance measurement "falls outside of a predetermined or programmable impedance range," then the electrode configuration will be changed and capture will again be attempted. (Col. 11, Lines 10-31). As discussed by the Applicant in the response to the previous Office Action, *Levine* discloses continuing capture detection with one less electrode while the Applicant's independent claims recite disabling ATP therapy.

In response to the Applicant's contentions, the Examiner stated on pages 2-3 of the Office Action that:

In light of the broadest interpretation of the claimed limitation, it is the Examiner's position that Levine disables ATP as taught in column 11, lines 11-20 when therapy is switched from one electrode configuration (for illustration purposes I will call this configuration A) to a different electrode configuration (configuration B), therapy is disabled on configuration A. Applicant did not claim disabling atrial ATP therapy delivery and not applying therapy elsewhere after the therapy is disable. (Emphasis original).

The Applicant respectfully submits that the Examiner is improperly applying the tenants of claim interpretation, leading to an erroneous claim interpretation. For example, the Examiner admits to applying "the broadest interpretation of the claimed limitation," even though claims must be given their broadest reasonable interpretation consistent with the specification. (MPEP § 2111; see *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005)). The Applicant respectfully submits that when the claims are properly interpreted, it is not necessary to amend the independent claims, as they are already patentable in view of the teachings of the *Levine* reference.

Independent claims 1, 20, 36, 61, and 62 each recite some variation of disabling ATP therapy. Because the therapy is disabled, as recited in the Applicant's base claims, it necessarily follows that the disabled therapy cannot be applied elsewhere (in its disabled state). The Applicant's claims do not recite disabling only a particular set of electrodes for delivering ATP therapy, as it may appear from the Examiner's interpretation. If the therapy itself is disabled, then it is moot whether another electrode set would be able to deliver the therapy.

The Applicant's independent claims 1, 20, 36, 61, and 62 each recite some variation of disabling ATP therapy in response to a measured impedance deviating from a threshold, which, as discussed in the response to the previous Office Action, is clearly not taught by *Levine*. Accordingly, *Levine* fails to teach each and every element and limitation of these independent claims.

Moreover, the Applicant respectfully submits that *Levine* does not disclose disabling ATP therapy in response to a measured impedance deviating from a threshold.

Levine discloses an auto-capture technique (Col. 10, Line 64-Col. 11, Line 4), and further discloses switching electrodes during auto-capture when a sensed impedance “falls outside of a predetermined or programmable impedance range” (Col. 11, Lines 10-31). Even so, *Levine*’s disclosure of switching electrodes for auto-capture does not constitute disabling ATP therapy.

For example, ATP is a therapy for treating tachycardia, tachycardia being characterized by an abnormally high heart rate. Auto-capture, on the other hand, is clearly not a therapy for treating tachycardia. Auto-capture, rather, is a procedure for determining pacing parameters for subsequent pacing therapy (i.e., the minimum energy required to effect capture of myocardial tissue). See *Levine*, Col. 1, Lines 42-44 and Col. 1, Line 61 – Col. 2, Line 39. The Applicant respectfully submits that one of ordinary skill in the art would readily understand that ATP therapy and auto-capture are distinct methodologies.

Although *Levine* lists anti-tachycardia pacing amongst other tiered therapies (Col. 8, Lines 51-52), *Levine*’s mere mention of anti-tachycardia pacing is unconnected with *Levine*’s discussion of switching electrodes during auto-capture.

For at least these reasons, the Applicant respectfully submits that *Levine*’s discussion of changing an electrode combination while performing an auto-capture procedure does not constitute a teaching of disabling ATP therapy. However, the Applicant’s claims recite further features which are not disclosed by *Levine*.

The Applicant’s independent claims 1, 36, and 61 each further recite, among other features, some variation of an impedance threshold developed for a particular patient.

Levine discloses “a predetermined or programmable impedance range” that when exceeded indicates a lead failure. (Col. 11, Lines 11-15). *Levine* does not disclose an impedance threshold developed for a particular patient. *Levine* does disclose customizing specified parameters for a particular patient. (Col. 8, Line 65-Col. 9, Line 7). However, these customizable parameters specified by *Levine* only include parameters for detecting

arrhythmia and delivery of a therapy (i.e. pulse amplitude, duration, rate, etc.) and do not include an impedance threshold developed for a particular patient. (*Id.*).

The Examiner maintains in the Office Action that *Levine* does disclose an impedance threshold developed for a particular patient. The Examiner supports this contention by stating “Levine meets this claimed limitation because included in the list of parameters that are developed for the particular patient is electrode polarity which is directly related to the characteristic of an impedance threshold and plays an integral part when measuring impedance as disclosed in the sections cited above [on Page 3 of the Office Action] and as set forth in said claimed limitation.” (Page 3).

The Applicant respectfully submits that *Levine*’s disclosure of selecting an electrode polarity for a patient does not constitute a teaching of developing an impedance threshold for a particular patient. In contrast to the Examiner’s statement that electrode polarity and impedance are directly related, the Applicant respectfully submits that one of ordinary skill in the art would understand that an impedance parameter measured between two electrodes may be the same after the electrode polarity is flipped for some configurations, while in other configurations the impedance value may be different upon flipping the electrode polarity. Moreover, implanted pacing electrodes of constant polarity can have different impedance value measurements taken between them over time (i.e., the impedance between two implanted pacing electrodes can change over time even though the respective polarity of the implanted pacing electrodes does not).

Moreover, regardless of whether impedance and polarity are directly related, disclosure of polarity selected for a patient is insufficient to teach an impedance threshold developed for a particular patient. An anticipatory reference requires that the “identical invention must be shown in as complete detail as is contained in the ... claim.” (*Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)). As such, the Applicant respectfully submits that electrode polarity selected for a particular patient does not constitute an impedance threshold developed for a particular patient, for at least the reason that these two features are not identical.

Claims 1, 36, and 61 each recite, among other limitations, some variation of an impedance threshold developed for a particular patient, which clearly is not disclosed by *Levine*.

The Applicant's independent claims 20 and 62 each further recite, among other features, some variation of measuring impedance, a capture threshold, and a sense amplitude, respectively associated with an atrial lead and comparing the impedance, capture threshold, and sense amplitude measurements with impedance, capture threshold, and sense amplitude limits, respectively.

Levine discloses an auto-capture technique which enables an impedance measuring circuit "whenever there is a failure to detect an evoked response (presumed loss of capture)." (Col. 11, Lines 1-3). *Levine*'s impedance measuring circuit then takes an impedance measurement and compares the measurement to a predetermined range. (Col. 11, Lines 4-15). *Levine* does not teach measuring a sense amplitude, nor does *Levine* teach comparing a capture threshold with a capture threshold limit or comparing a sense amplitude measurement with a sense amplitude limit.

In addressing the Applicant's position that *Levine* does not teach measuring impedance, a capture threshold, and a sense amplitude, respectively associated with an atrial lead and comparing the impedance, capture threshold, and sense amplitude measurements with impedance, capture threshold, and sense amplitude limits, respectively, the Examiner states that:

Not only do the sections pointed to by the Examiner read on said claimed limitations (e.g., column 7, lines 59 and 65; column 10, lines 12-13 and 28-30 and column 10, lines 35-55), but, it is inherent that the device, and many like it in the art, inherently perform said claimed limitations because sense amplifiers coupled with leads and all other associated circuitry of the device have to perform various comparisons and threshold checks on a consistent and regular basis in order to negotiate and execute the various functions and therapies that the device provides. (Office Action, Page 4)

The Applicant respectfully submits that the portions of *Levine* cited by the Examiner do not support the Examiner's contention. For example, Column 7, Lines 59 and 65 respectively disclose timing control circuitry 79 and evoked response windows. Column 10, Lines 12-13 and Lines 28-30 respectively disclose detection circuitry for detecting evoked responses and a data acquisition system 90 for measuring the amplitude of a cardiac signal of an evoked response (See Col. 10, Lines 18-27). Column 10, Lines 35-55 discloses how auto-capture features scan for a capture threshold by delivering successive pacing pulses with decrements in energy level while sensing for evoked responses.

The Applicant respectfully submits that the cited portions of *Levine* clearly fail to disclose an embodiment that includes measuring impedance, a capture threshold, and a sense amplitude, respectively associated with an atrial lead and comparing the impedance, capture threshold, and sense amplitude measurements with impedance, capture threshold, and sense amplitude limits, respectively.

Moreover, the Applicant respectfully submits that the recited features of the claims are not inherently used in *Levine's* device, or others like it, contrary to the Examiner's contention.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. (*In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art)).

"To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." (*In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)).

The Examiner posits that *Levine's* pacing device inherently performs the recited claim limitations because such pacing devices have to perform various comparisons and threshold checks. The Applicant respectfully submits that the Examiner is impermissibly speculating on what *Levine* might do to substitute for actual teachings of *Levine*.

The contention that *Levine's* pacing device inherently measures impedance, a capture threshold, and a sense amplitude, respectively associated with an atrial lead and compares the impedance, capture threshold, and sense amplitude measurements with impedance, capture threshold, and sense amplitude limits, respectively, is in error, for at least the reason that *Levine's* pacing device does not necessarily perform each of these steps. While it is the case that some pacing devices may sense signals and use thresholds and the like to operate, *Levine's* pacing device need not use each of the particular parameter measurements and limits recited in claims 20 and 62. For example, the Applicant respectfully submits that a pacing device can operate without an impedance limit or a sense amplitude limit.

Accordingly, the features recited in the Applicant's claims 20 and 62 are not necessarily present in *Levine's* pacing device, and therefore are not inherently disclosed by *Levine*.

In light of the above arguments, the Applicant respectfully submits that the *Levine* reference does not teach each and every element and limitation of independent claims 1, 20, 36, 61, and 62. As such, these claims are not anticipated by *Levine* and the anticipation rejection of these claims must be withdrawn.

Dependent claims 2-3, 10-19, 24-27, 37-39, 44-55, and 59-60, which are dependent from independent claims 1, 20, 36, 61, and 62, respectively, were also rejected under 35 U.S.C. §102(e) as being unpatentable over *Levine*. While the Applicant does not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1, 20, 36, 61 and 62. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims

from the cited reference. Therefore, dependent claims 2-3, 10-19, 24-27, 37-39, 44-55, and 59-60 are also not anticipated by *Levine*.

As such, the Applicant respectfully requests withdrawal of the §102(e) rejection of claims 1-3, 10-19, 20, 24-27, 36-39, 44-55, and 59-62 and notification that these claims are in condition for allowance.

Claims 4-8, 21-23, 28-29, 40-43, and 56-58 are rejected based on 35 U.S.C. §103(a) as being unpatentable over *Levine*.

Each of claims 4-8, 21-23, 28-29, 40-43, and 56-58 depend from one of independent claims 1, 20, and 36, respectively. Independent claims 1, 20, and 36 are not obvious for at least the reason that *Levine* fails to teach or suggest each and every limitation recited in each claim. Furthermore, while the Applicant does not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1, 20, and 36. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited reference. Moreover, if an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Therefore, dependent claims 4-8, 21-23, 28-29, 40-43, and 56-58 are not made obvious by *Levine*.

As such, the Applicant respectfully requests withdrawal of the §103(a) rejection of claims 4-8, 21-23, 28-29, 40-43, and 56-58 and notification that these claims are in condition for allowance.

Claims 36-60 stand rejected under 35 U.S.C. §112, ¶2, as being indefinite for failing to particularly point out and distinctly claim the subject matter. The Applicant respectfully maintains the previously recited position with respect to the §112, ¶2, objections to claims 36-60.

With regard to these objections, the Applicant draws the Examiner's attention to MPEP § 2173.02, stating that:

[the Examiner] should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. Examiners are encouraged to suggest claim language to applicants to improve the clarity or precision of the language used (emphasis original).

The Applicant respectfully submits that claims 36-60 define patentable subject matter with the requisite reasonable degree of particularity and distinctness and would reasonably apprise one of ordinary skill in the art of the scope of the claims. (See *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366, 71 USPQ2d 1081, 1089 (Fed. Cir. 2004) ("The requirement to 'distinctly' claim means that the claim must have a meaning discernible to one of ordinary skill in the art when construed according to correct principles....Only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite.")).

The Applicant further references *In re Larsen*, as noted in MPEP § 2173.05(e), where the Examiner rejected the claim under 35 U.S.C. § 112, ¶2, because the omission from the claim's preamble of a critical element (i.e., a linear member) renders that claim indefinite. (No. 01-1092 (Fed. Cir., 2001) (unpublished)). The court reversed the Examiner's rejection and stated that the totality of all the limitations of the claim and their interaction with each other must be considered to ascertain the inventor's contribution to the art. (*Id.*). Upon review of the claim in its entirety, the court concluded that the claim at issue apprised one of ordinary skill in the art of its scope and, therefore, served the notice function required by 35 U.S.C. § 112, ¶ 2. (*Id.*).

Although the Examiner's objections in the present case do not concern the preambles of the claims, the Applicant respectfully submits that the same principles of claim interpretation are relevant. Specifically, the totality of all of the limitations of each claim and the relationships between them apprise one of ordinary skill in the art of the

respective scope of each claim and therefore satisfies § 112, ¶2. Accordingly, it is unnecessary to narrow the claims with amendments linking limitations to fit the particular claiming style desired by the Examiner when the claims already satisfy the spirit and letter of § 112, ¶2.

Furthermore, to any extent that one of ordinary skill in the art is unable to reasonably discern the scope of the claims from the face of the claims themselves, MPEP § 2173.02 clearly sanctions reference to clarifying portions of the Specification. The Applicant below cites such portions of the Specification which provide examples of how the various claim features interact, thus ensuring the claims to be reasonably definite to one of ordinary skill in the art.

In specific regard to the §112, ¶2 rejection of claim 36, the Examiner states that the phrase “coupled to memory” is vague and that it is unclear if the memory is positively or functionally recited. The Applicant respectfully submits that skilled artisans know that memory is structure, and that a control system coupled to memory is a well understood structural arrangement.

In further regard to the §112, ¶2 rejection of claim 36, the Examiner states that it is unknown which element provides the atrial therapy referred to in claim 36. The Applicant respectfully submits that one of ordinary skill in the art would understand that a combination of the recited elements provides the atrial therapy referred to in claim 36. Moreover, the Applicant’s Specification provides further support for understanding claim 36 and resolving the Examiner’s stated concerns, including but not limited to Page 6, Lines 1-7; Page 6, Line 2 – Page 7, Line 2; Page 7, Lines 14-24 and Fig. 2.

In regard to the §112, ¶2 rejection of claims 37-39, the Examiner states that the phrase “the impedance threshold . . . lead impedance measurement” is vague and that it is unclear which element is performing the function in each claim. Also, in regard to the §112, ¶2 rejection of claims 40-41, the Examiner states that the phrase “the impedance threshold . . . measure impedance” is vague and that it is unclear which element is performing the function in each claim. In further regard to the §112, ¶2 rejection of claims 46-48, the Examiner states that the phrase “the predetermined factor . . . the impedance

threshold” is vague and that it is unclear which element is performing the function in each claim. The Applicant respectfully submits that one of ordinary skill in the art would understand that a combination of the recited elements measures impedance and stores the predetermined factor and impedance threshold. Moreover, the Applicant’s Specification provides further support for understanding claims 37-39, 40-41 and 46-48 and resolving the Examiner’s stated concerns, including but not limited to Page 6, Lines 8-15; Page 6, Line 21-Page 7, Line 2; Page 12, Line 4-Page 14, Line 17; Page 17, Lines 19-29 and Fig. 2.

In regard to the §112, ¶2 rejection of claim 49, the Examiner states that the phrase “a pace pulse” is vague and that it is unclear what element is providing a pace pulse. The Applicant respectfully submits that one of ordinary skill in the art would understand that the pace pulse is provided by a combination of the recited elements of independent claim 36 and dependent claim 49. Moreover, the Specification provides further support for understanding claim 49 and the pace pulse, including but not limited to Page 20, Lines 8-13.

In regard to the §112, ¶2 rejection of claim 50, the Examiner states that the phrase “a stimulus delivered” is vague and that it is unclear what element is providing a stimulus. The Applicant respectfully submits that one of ordinary skill in the art would understand that the stimulus is provided by a combination of the recited elements of independent claim 36 and dependent claim 50. Moreover, the Specification provides further support for understanding claim 50 and the stimulus, including but not limited to Page 6, Lines 1-7; Page 6, Line 2 – Page 7, Line 2; Page 7, Lines 14-24; Page 13, Line 29-Page 14, Line 5 and Fig. 2.

In regard to the §112, ¶2 rejection of claims 51 and 53, the Examiner states that the phrase “after detection of an atrial arrhythmic event” is vague and that it is unclear what element is providing detection of an atrial arrhythmic event. An atrial arrhythmic event is not something provided by the elements of the claims, but rather is something to which elements of the claims are responding. Also, the Applicant respectfully submits that one of ordinary skill in the art would understand that detection of an atrial arrhythmic event is provided by a combination of the recited elements of dependent claims 51 and 53, respectfully, and independent claim 36. Moreover, the Specification provides further

support for understanding claim 51 and the detection of an atrial arrhythmic event, including but not limited to Page 6, Line 8-Page 9, Line 4; Page 19, Lines 25-30 and Fig. 2.

In regard to the §112, ¶2 rejection of claims 52 and 54, the Examiner states that the phrase “after detection of an atrial arrhythmic episode” is vague and that it is unclear what element is providing an atrial arrhythmic episode. The recitation of an atrial arrhythmic episode in claims 52 and 54 is not included as an element or as a function within the claim. Rather, one of ordinary skill in the art would understand that an atrial arrhythmic event is something to which elements of the respective claims are responding.

As such, the Applicant submits that claims 36-60 are in compliance with §112, ¶2 and request withdrawal of the §112, ¶2 rejections to claims 36-60.

It is to be understood that the Applicant does not acquiesce to the Examiner’s characterization of the asserted art or the Applicant’s claimed subject matter, nor of the Examiner’s application of the asserted art or combinations thereof to the Applicant’s claimed subject matter. Moreover, the Applicant does not acquiesce to any explicit or implicit statements or conclusions by the Examiner concerning what would have been obvious to one of ordinary skill in the art, obvious design choices, alternative equivalent arrangements, common knowledge at the time of the Applicant’s invention, inherent, officially noticed facts, and the like. The Applicant respectfully submits that a detailed discussion of each of the Examiner’s rejections beyond that provided above is not necessary, in view of the clear absence of teaching and suggestion of various features recited in the Applicant’s pending claims. The Applicant, however, reserves the right to address in detail the Examiner’s characterizations, conclusions, and rejections in the future.

Authorization is given to charge Deposit Account No. 50-3581 (GUID.014US01) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,

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